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ANNEX V

TRANSFORMATION OF ANIMAL BY-PRODUCTS AND DERIVED PRODUCTS INTO BIOGAS, COMPOSTING

CHAPTER III

TRANSFORMATION PARAMETERS

Section 2

Alternative transformation parameters for biogas and composting plant

1. The competent authority may authorise the use of parameters other than the parameters set out in point 1 of Section 1 of Chapter I and other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration shall include a validation, which shall be carried out in accordance with the following requirements:
 - (a) Identification and analysis of possible hazards, including the impact of input material, based on a full description of the transformation conditions and parameters;
 - (b) A risk assessment, which evaluates how the specific transformation conditions referred to in point (a) are achieved in practice under normal and atypical situations;
 - (c) Validation of the intended process by measuring the reduction of viability/infectivity of:
 - (i) endogenous indicator organisms during the process, where the indicator is:
 - consistently present in the raw material in high numbers,
 - not less heat resistant to the lethal aspects of the transformation process, but also not significantly more resistant than the pathogens for which it is being used to monitor,
 - relatively easy to quantify and to identify and to confirm; or
 - (ii) a well-characterised test organism or virus, during exposure, introduced in a suitable test body into the starting material.
 - (d) The validation of the intended process referred to in point (c) must demonstrate that the process achieves the following overall risk reduction:
 - (i) for thermal and chemical processes by:
 - a reduction of 5 log₁₀ of *Enterococcus faecalis* or *Salmonella Senftenberg* (775W, H₂S negative),
 - reduction of infectivity titre of thermoresistant viruses such as parvovirus by at least 3 log₁₀, whenever they are identified as a relevant hazard; and
 - (ii) as regards chemical processes also by:
 - a reduction of resistant parasites such as eggs of *Ascaris* sp. by at least 99,9 % (3 log₁₀) of viable stages;

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- (e) Designing a complete control programme including procedures for monitoring the functioning of the process referred to in point (c);
- (f) Measures ensuring continuous monitoring and supervision of the relevant process parameters fixed in the control programme when operating the plant.

Details on the relevant process parameters used in a biogas or composting plant as well as other critical control points must be recorded and maintained so that the owner, operator or their representative and the competent authority can monitor the operation of the plant.

Records must be made available by the operator to the competent authority on request. Information relating to a process authorised under this point must be made available to the [^{F1}appropriate authority] on request.

Textual Amendments

- F1** Words in Annex 5 Ch. 3 Section 2 point 1 substituted (E.W.S.) (31.12.2020) by [The Animals, Aquatic Animal Health, Invasive Alien Species, Plant Propagating Material and Seeds \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1388\)](#), regs. 1(2)(c), **13(39)(a)**

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